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Test Drive Unlimited Patch 1.68 B 121

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Figure 1. Study Designs and Endpoints

	LAHG (NCT03012334)	LAIF (NCT03459612)
Study Design and Population	Phase 1, single-center, randomized, subject- and investigator-blind, single-dose, placebo- and active-controlled, full 5-period crossover study	Phase 1, multicenter, randomized, subject- and investigator-blind, placebo- and active- controlled, full 4-period crossover study
	90 healthy adult subjects who were active drivers with no history of sleep disorder, substance abuse, or concomitant stimulant or sleep aid use	68 healthy adult subjects who were active drivers with no history of sleep disorder, substance abuse, or concomitant stimulant or sleep aid use
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Study Treatments	Lasmiditan, single oral dose of 50, 100, or 200 mg	Lasmiditan, oral dose of 100 or 200 mg (single dose at start of each period)
	Alprazolam, single oral dose of 1 mg	Diphenhydramine, oral doses of 50 mg (dosed 2 hours before each driving test time point)
	Placebo, single oral dose	Placebo, oral doses (whenever active drug not dosed to maintain blind)
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Study Time Points	Driving test time point: 1.5 hours postdose	Driving test time points: 8, 12, 24 hours postdose (relative to lasmiditan dosing)
	Lasmiditan pharmacokinetic sampling time point: predose and following conclusion of driving test (2.58 hours postdose)	Lasmiditan pharmacokinetic sampling time point: predose and up to 48 hours postdose
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Primary Endpoint	Standard Deviation of Lateral Position (SDLP) using the Cognitive Research Corporation Driving Simulator (CRCDS)-MiniSim: subjects instructed to drive a 100-km highway segment with steady lane position and constant speed	
Performance CogScreen Symbol Digit Coding (SD standard deviation of reaction time Driving Performance Lane exceedance: number, maximum		motivation, driving performance appraisal mber of correct responses, response accuracy, exceedance area
	Speed: average speed, deviation, count Excessive Ay (cornering speed threshold) Number of collisions Divided attention: correct responses, omission and commission errors, reaction time, standard deviation of reaction times	
Safety Assessments	Adverse events, clinical laboratory tests	

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